HFL-55

m41690

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

September 8, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-00-4262

Mark W. Auckerman
Vice President/Co-Owner
Mark II Enterprises
DBA Med Ox Home Medical
74 North Plaza Blvd.
Chillicothe, Ohio 45601

Dear Mr. Auckerman:

During a FDA inspection on August 15-16, 2000 of your medical oxygen transfilling facility, Med Ox Home Medical located at the above address, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21 Code of Federal Regulations, Parts 210 and 211). These deviations cause your medical gas, compressed Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the ACT).

Our investigations revealed that your firm does not adequately test your compressed medical oxygen before it is distributed. Your firm uses a non-official test procedure (an [redacted] Model [redacted] oxygen analyzer) to assay your compressed oxygen for identity and strength. This test procedure has not been adequately validated to show that its sensitivity and accuracy will produce identity and strength results equivalent or superior to those obtained using the official method described in the U.S. Pharmacopoeia (USP).

The above-described violations are not intended to be an all-inclusive list of the deficiencies at your medical gas facility. Your firm has four other medical gas transfilling facilities, which are located in Cambridge, Ohio; Elyria, Ohio; Springfield, Ohio; and Zanesville, Ohio. It is your responsibility to assure that current regulations applicable to your medical gas transfilling operations are adhered to at all branches of your firm's medical gas transfilling facilities.

Federal agencies are advised of the issuance of all FDA Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct the violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct the violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District